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COMMONWEALTH OF VIRGINIA

STATE CORPORATION COMMISSION

AT RICHMOND, MAY 2, 2000

COMMONWEALTH OF VIRGINIA, ex rel.

STATE CORPORATION COMMISSION

Ex Parte: In the matter of Adopting Revisions to the Rules Governing Independent External Review of Final Adverse Utilization Review Decisions

CASE NO. INS000098

ORDER TO TAKE NOTICE

WHEREAS, § 12.1-13 of the Code of Virginia provides that the Commission shall have the power to promulgate rules and regulations in the enforcement and administration of all laws within its jurisdiction, and § 38.2-223 of the Code of Virginia provides that the Commission may issue any rules and regulations necessary or appropriate for the administration and enforcement of Title 38.2 of the Code of Virginia;

WHEREAS, § 38.2-5905 of the Code of Virginia provides that the Commission shall promulgate regulations effectuating the purpose of Chapter 59 of Title 38.2 of the Code of Virginia;

WHEREAS, the rules and regulations issued by the Commission pursuant to § 38.2-223 of the Code of Virginia are set forth in Title 14 of the Virginia Administrative Code;

WHEREAS, the Bureau of Insurance has submitted to the Commission proposed revisions to Chapter 215 of Title 14 of the

Virginia Administrative Code entitled "Rules Governing Independent External Review of Final Adverse Utilization Review Decisions," which amend the rules at 14 VAC 5-215-30 through 14 VAC 5-215-70 and 14 VAC 5-215-110;

WHEREAS, the proposed revisions reflect amendments to certain sections of Chapter 59 of Title 38.2 of the Code of Virginia enacted by the General Assembly of Virginia in its 2000 session; and

WHEREAS, the Commission is of the opinion that the proposed revisions should be adopted with an effective date of July 1, 2000;

THEREFORE, IT IS ORDERED THAT:

(1) The proposed revisions to the "Rules Governing Independent External Review of Final Adverse Utilization Review Decisions," which amend 14 VAC 5-215-30 through 14 VAC 5-215-70, and 14 VAC 5-215-110, be attached hereto and made a part hereof;

(2) All interested persons TAKE NOTICE that the Commission shall enter an order subsequent to June 1, 2000, adopting the revisions proposed by the Bureau of Insurance unless on or before June 1, 2000, any person objecting to the proposed revisions files a request for a hearing to oppose the adoption of the proposed revisions, with an effective date of July 1, 2000, with the Clerk of the Commission, Document Control Center, P.O. Box 2118, Richmond, Virginia 23218;

(3) All interested persons TAKE NOTICE that on or before June 1, 2000, any person desiring to comment in support of, or in opposition to, the proposed revisions shall file such comments in writing with the Clerk of the Commission at the above address;

(4) All filings made under paragraphs (2) or (3) above shall contain a reference to Case No. INS000098.

(5) AN ATTESTED COPY hereof, together with a copy of the proposed revisions, be sent by the Clerk of the Commission to the Bureau of Insurance in care of Deputy Commissioner Gerald A. Milsky, who forthwith shall give further notice of the proposed adoption of the revisions to the rules by mailing a copy of this Order, together with a draft of the proposed revisions, to all insurers licensed by the Commission to write accident and sickness insurance in the Commonwealth of Virginia, and all health services plans, health maintenance organizations, and dental or optometric services plans licensed by the Commission under Chapters 42, 43, and 45, respectively, of Title 38.2 of the Code of Virginia; and

(6) The Bureau of Insurance shall file with the Clerk of the Commission an affidavit of compliance with the notice requirements of paragraph (5) above.

STATE CORPORATION COMMISSION
BUREAU OF INSURANCE

CHAPTER 215.

Rules Governing Independent External Review of Final Adverse Utilization Review Decisions.

14 VAC 5-215-30. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise.

~~"Adverse decision" means a utilization review determination by the utilization review entity that the health care service rendered or proposed to be rendered was or is not medically necessary, when such determination may result in noncoverage of the health care service.~~

"Appellant" means (i) the covered person; (ii) the covered person's parent, guardian, legal custodian, or other individual authorized by law to act on behalf of the covered person, if the covered person is a minor; (iii) the covered person's spouse, parent, committee, legal guardian, or other individual authorized by law to act on behalf of the covered person, if the covered person is not a minor but is incompetent or incapacitated; or (iv) the covered person's treating health care provider acting with the consent of the covered person, the covered person's parent, guardian, legal custodian, or other individual authorized by law to act on behalf of the covered person, if the covered person is a minor, or the covered person's spouse, parent, committee, legal guardian, or other individual authorized by law to act on behalf of the covered person, if the covered person is not a minor but is incompetent or incapacitated.

"Commission" means the Virginia State Corporation Commission.

"Commissioner" means the Commissioner of Insurance.

"Covered person" means ~~a subscriber, policyholder, member, enrollee or dependent, as the case may be, under a policy or contract issued or issued for delivery in Virginia by a managed care health insurance plan licensee, insurer, health services plan, or preferred provider organization~~ an individual,

whether a policyholder, subscriber, enrollee, covered dependent, or member of a managed care health insurance plan, who is entitled to health care services or benefits provided, arranged for, paid for or reimbursed pursuant to a managed care health insurance plan as defined in and subject to regulation under Chapter 58 (§38.2-5800 et seq.) of Title 38.2 of the Code of Virginia, when such coverage is provided under a contract issued in this Commonwealth.

"Emergency health care" means health care items and medical services furnished or required to evaluate and treat an emergency medical condition.

"Emergency medical condition" means the sudden and, at the time, unexpected onset of a health condition or illness that requires immediate medical attention, the absence of which would result in a serious impairment to bodily functions, serious dysfunction of a bodily organ or part, or would place the person's health in serious jeopardy. "Emergency medical condition" also means a health condition or illness that if not treated within the time frame allotted for a standard review under this chapter will result in a serious impairment to bodily functions, serious dysfunction of a bodily organ or part, or would place the person's health in serious jeopardy.

"Evidence of coverage" means any certificate, individual or group agreement or contract, or identification card or related documents issued in conjunction with the certificate, agreement or contract, issued to a subscriber setting out the coverage and other rights to which a covered person is entitled.

"Final adverse decision" means a utilization review determination ~~made by a utilization review entity in~~: (i) declining to grant an expedited review in a situation involving an alleged emergency medical condition; (ii) declining to provide coverage or services for an alleged emergency medical condition, whether before or after granting an expedited review; or (iii) ~~a reconsideration of a prior adverse decision, and upon which a covered person or a treating health care provider acting with the consent of a covered person may base an appeal~~ denying benefits or coverage, and concerning which all internal appeals available to the covered person pursuant to Title 32.1 of the Code of Virginia have been exhausted. For

purposes of this chapter, a final adverse decision shall be deemed to have been made on the date that it is communicated to the covered person or treating health care provider.

"Treating health care provider" or "provider" means a licensed health care provider who renders or proposes to render health care services to a covered person.

"Utilization review" means a system for reviewing the necessity, appropriateness, and efficiency of hospital, medical or other health care services rendered or proposed to be rendered to a patient or group of patients for the purpose of determining whether such services should be covered or provided by an insurer, health services plan, managed care health insurance plan licensee, or other entity or person. As used herein, "utilization review" shall include, but shall not be limited to, preadmission, concurrent and retrospective medical necessity determination, and review related to the appropriateness of the site at which services were or are to be delivered.

"Utilization review" shall also include determinations of medical necessity based upon contractual limitations regarding "experimental" or "investigational" procedures, by whatever terms designated in the evidence of coverage. "Utilization review" shall not include any: (i) denial of benefits or services for a procedure which is explicitly excluded pursuant to the terms of the contract or evidence of coverage; (ii) review of issues concerning contractual restrictions on facilities to be used for the provision of services; or (iii) determination by an insurer as to the reasonableness and necessity of services for the treatment and care of an injury suffered by an insured for which reimbursement is claimed under a contract of insurance covering any classes of insurance defined in §§ 38.2-117 through 38.2-119, 38.2-124 through 38.2-126, 38.2-130 through 38.2-132, and 38.2-134 of the Code of Virginia.

"Utilization review entity" or "entity" means ~~a person or entity performing utilization review~~ an insurer or managed care health insurance plan licensee that performs utilization review or upon whose behalf utilization review is performed with regard to the health care or proposed health care that is the subject of the final adverse decision.

14 VAC 5-215-40. Minimum appealable amount.

A. Appeals of final adverse decisions may be made to the Bureau of Insurance provided that the actual cost of the health care service or services to the covered person would exceed ~~$500~~ 300 if the final adverse decision is not reversed. The cost of the health care service or services shall be determined by the amount the covered person has paid or has incurred a legal obligation to pay for such service or services, as well as the amount that the covered person would be obligated to pay in the event that the final adverse decision is not reversed.

B. The health care service or services must meet the following criteria in order to be eligible for an external review as provided by this chapter:

1. The service or services, as described by the most recent published editions of the applicable International Classification of Diseases 9th Revision Clinical Modification, Physician's Current Procedural Terminology, Diagnostic Related Groups, or other billing code, must have a minimum value, as defined in 14 VAC 5-215-40 A, that exceeds ~~$500~~ 300.

2. No covered person or provider shall engage in "bundling" techniques designed to combine the value of denied services such that the actual cost to the covered person of denied services artificially exceeds ~~$500~~ 300.

3. The commissioner, or his designee, shall have the final undisputed authority to determine if the actual cost to the covered person of the denied services exceeds ~~$500~~ 300.

14 VAC 5-215-50. Appeals.

A. An appeal of a final adverse decision made by a utilization review entity shall be submitted to the Bureau of Insurance within 30 days of the final adverse decision. The appeal shall be made by: (i) completing and signing a copy of the then current "Appeal of Final Adverse Decision" form, or such other form or forms as may then be required by the Bureau of Insurance pursuant to 14 VAC 5-215-120; (ii) completing and signing an "Authorization to Release Medical Information" in a form and manner

required by the Bureau of Insurance; and (iii) forwarding a check or money order made payable to the "Treasurer of Virginia" in the amount of $50. The Bureau of Insurance shall provide a copy of the written appeal to the utilization review entity that made the final adverse decision.

B. The $50 fee required to file an appeal may be waived or refunded for good cause shown upon a determination by the Bureau of Insurance that payment of the filing fee will cause undue financial hardship for the covered person. Such determination shall be based upon information provided on the "Appeal of Final Adverse Decision" form then required by the Bureau of Insurance, and any supplemental information required by the Bureau of Insurance. The decision of the Bureau of Insurance as to whether good cause has been shown that payment of the filing fee will cause undue financial hardship shall be final.

C. A preliminary review of the appeal shall be conducted by the Bureau of Insurance or its designee to determine the following: (i) that the person on whose behalf the appeal has been filed is, or was, a covered person at the time the health care service in question was requested; (ii) that the appellant satisfies the definition of "appellant" set forth in 14 VAC 5-215-30; (iii) that the benefit or service that is the subject of the appeal reasonably appears to be a covered service for which the actual cost to the covered person would exceed ~~$500~~ 300 if the final adverse decision is not reversed; (iv) that all other appeal procedures available to the appellant have been exhausted, except in the case of an appeal accepted as one requiring expedited review; and (v) that the appeal is otherwise complete and filed in accordance with this section. The Bureau of Insurance shall not accept an appeal that does not meet the foregoing requirements.

D. The preliminary review shall be conducted within ~~five~~ 10 working days of receipt of all information and documentation necessary to conduct the preliminary review.

E. The Bureau of Insurance shall notify the appellant and the utilization review entity in writing within ~~three~~ five working days of the completion of the preliminary review whether the appeal has been accepted for review, and if not accepted, the reason or reasons therefor.

F. The appellant, the treating health care provider, if not the appellant, and the utilization review entity shall provide to the Bureau of Insurance or its designee copies of all medical records relevant to the final adverse decision within ~~10~~ 20 working days after the Bureau of Insurance has mailed, via certified mail, return receipt requested, written notice of its acceptance of the appeal. Failure to comply with such request within the required time may result in the dismissal of the appeal or reversal of the final adverse decision, at the discretion of the commissioner. The confidentiality of these medical records shall be maintained in accordance with the confidentiality and disclosure laws of the Commonwealth.

G. The Bureau of Insurance, or its designee, may request additional medical records from the appellant, the treating health care provider, if not the appellant, or the utilization review entity. Such medical records shall be provided to the entity making the request, whether the Bureau of Insurance or its designee, within ~~10~~ 20 working days of the request. The confidentiality of these medical records shall be maintained in accordance with the confidentiality and disclosure laws of the Commonwealth. Failure to comply with the request within the required time may result in dismissal of the appeal or reversal of the final adverse decision at the discretion of the commissioner.

H. The commissioner, upon good cause shown, may provide an extension of time for the covered person, the treating health care provider, the utilization review entity and the Bureau of Insurance to meet the time requirements set forth in this section.

~~H~~I. If an appeal that is reviewed as an expedited appeal by a utilization review entity results in a final adverse decision, the utilization review entity shall take the following actions immediately: (i) notify the person who requested the expedited review of the final adverse decision; and (ii) notify the appellant, by telephone, telefacsimile, or electronic mail, that the appellant is eligible for an expedited

appeal to the Bureau of Insurance without the necessity of providing the justification required pursuant to subdivision 1 of 14 VAC 5-215-80. The notification shall be followed within 24 hours by written notice to the appellant and the treating health care provider, if not the appellant, clearly informing them of the right to appeal this decision to the Bureau of Insurance and providing the appropriate forms by which such appeal to the Bureau of Insurance may be filed. A copy of this written notice shall be retained by the utilization review entity and included with any materials forwarded to the Bureau of Insurance in the event the utilization review entity's decision is appealed to the Bureau of Insurance.

~~I~~J. If a request for an expedited review is denied by a utilization review entity, the entity shall take the following actions immediately: (i) notify the appellant of the decision by telephone, telefacsimile, or electronic mail; and (ii) inform the appellant that the appellant has the right to file a request for an expedited appeal with the Bureau of Insurance pursuant to subdivision 1 of 14 VAC 5-215-80. This notification shall be followed within 24 hours by a written notice to the appellant and the treating health care provider, if not the appellant, clearly informing them of the right to appeal this decision to the Bureau of Insurance and providing the appropriate forms by which such appeal to the Bureau of Insurance may be filed. A copy of the written notice shall be retained by the utilization review entity and included with any materials forwarded to the Bureau of Insurance in the event the utilization review entity's decision is appealed to the Bureau of Insurance.

~~J~~K. If the Bureau of Insurance, or its designee, determines that a request for an expedited review which has been reviewed in accordance with subsection ~~I~~ J of this section does not meet its criteria for an expedited review, the appellant shall be notified in writing by the Bureau of Insurance, or its designee, within two working days from the time such determination is made. The notice shall instruct the appellant wishing to pursue the appeal to contact the issuer of coverage and request a review through the standard review process of the issues for which an expedited review was sought.

14 VAC 5-215-60. Impartial health entity.

The Bureau of Insurance shall contract with one or more impartial health entities to perform the review of final adverse decisions made by utilization review entities. The impartial health entity shall examine the final adverse decision and determine whether the decision is objective, clinically valid, compatible with established principles of health care, and appropriate under the terms of the contractual obligations to the covered person. The impartial health entity shall issue its written recommendation affirming, modifying, or reversing the final adverse decision within 30 working days of the ~~acceptance of the appeal by the Bureau of Insurance~~ date that the impartial health entity has received from all parties all documentation and information necessary for it to complete its review in the case of a standard review as set forth in 14 VAC 5-215-70. In the case of an expedited review, the impartial health entity shall issue its written recommendation within five working days of the acceptance of the appeal by the Bureau of Insurance.

14 VAC 5-215-70. Standard review.

A. The Bureau of Insurance, within ~~two~~ five working days following its acceptance of an appeal, shall assign an impartial health entity with which it has contracted pursuant to 14 VAC 5-215-60 to conduct an external review and to provide a written recommendation to the commissioner as to whether to affirm, modify, or reverse the final adverse decision.

B. In reaching a recommendation, the assigned impartial health entity is not bound by any decisions or conclusions reached during the utilization review entity's utilization review process.

C. In lieu of providing records to the Bureau of Insurance pursuant to 14 VAC 5-215-50 F, the utilization review entity, the appellant or the treating health care provider, if not the appellant, shall provide to the assigned impartial health entity all documents, medical records, and other information relevant to and relied upon by the utilization review entity in reaching its final adverse decision within ~~10~~ 20 working days after the Bureau of Insurance has mailed written notice of its acceptance of the appeal

pursuant to 14 VAC 5-215-50 E. The confidentiality of medical records shall be maintained in accordance with the confidentiality and disclosure laws of the Commonwealth.

D. Except as provided in subsection E of this section, failure of the utilization review entity to provide the documents, medical records and information within the time specified in subsection C of this section shall not delay the conduct of the external review.

E. 1. Upon receipt of a notice from the assigned impartial health entity that the utilization review entity, appellant, or the treating health care provider, if not the appellant, has failed, without good cause, as determined by the commissioner in his sole discretion, to provide the documents, medical records, and information within the time specified in subsection C of this section, the commissioner may terminate the external review and make a decision to affirm or reverse the final adverse decision.

2. Immediately upon making the decision pursuant to subdivision 1 of this subsection, the commissioner shall communicate his decision in writing to the assigned impartial health entity, the appellant and the utilization review entity.

F. The assigned impartial health entity shall review all of the relevant information and documents received pursuant to subsection C of this section and any other information submitted in writing by the appellant that has been forwarded to the impartial health entity by the Bureau of Insurance.

G. In addition to the documents and information provided pursuant to subsection C of this section, the assigned impartial health entity, to the extent the information is available and the impartial health entity considers them appropriate, shall consider the following in making its recommendation:

1. The treating health care provider's recommendation;

2. Consulting reports from appropriate health care providers and other documents submitted by the utilization review entity, the appellant, or the covered person's treating health care provider, if not the appellant;

3. The terms of coverage under the covered person's health benefit plan;

4. The most appropriate practice guidelines, which may include generally accepted practice guidelines, evidence-based practice guidelines or any other practice guidelines developed by the federal government, national or professional medical societies, boards and associations; and

5. Any applicable clinical review criteria developed or used by the utilization review entity.

H. The assigned impartial health entity shall include in its recommendation provided pursuant to 14 VAC 5-215-60:

1. A general description of the reason or reasons for the request for external review;

2. The date the impartial health entity received the assignment from the Bureau of Insurance to conduct the external review;

3. The dates the external review began and concluded;

4. The date of its recommendation;

5. The principal reason or reasons for its recommendation;

6. The rationale for its recommendation; and

7. References to the evidence or documentation, including the practice guidelines or clinical criteria, considered in reaching its recommendation.

I. 1. Immediately upon receipt of the assigned impartial health entity's recommendation, the commissioner shall review the recommendation to ensure that it is not arbitrary or capricious.

2. The commissioner shall notify the appellant and the utilization review entity in writing of the decision to uphold or reverse the final adverse decision by issuing a written ruling affirming, modifying or reversing the final adverse decision. The written ruling shall bind the covered person and the issuer of the covered person's policy or contract for health benefits to the same extent to which each would have been bound by a judgment entered in an action at law or in equity with respect to the issues which the impartial health entity may examine when reviewing a final adverse decision.

3. The commissioner shall include in the notice sent pursuant to subdivision 2 of this subsection:

a. The principal reason or reasons for the decision, including, as an attachment to the notice or in any other manner that the commissioner considers appropriate, the information provided by the assigned impartial health entity supporting its recommendation; and

b. If applicable, the principal reason or reasons why the commissioner did not follow the assigned impartial health entity's recommendation.

4. Upon notice of a decision pursuant to subdivision 1 of this subsection reversing the final adverse decision, the utilization review entity immediately shall approve and provide, or provide reimbursement for, any and all medical services that were the subject of the final adverse decision.

14 VAC 5-215-110. Standards, credentials, and qualifications of the impartial health entity.

A. In order to qualify to perform either standard or expedited external reviews pursuant to this chapter and § 38.2-5900 et seq. of the Code of Virginia, an impartial health entity shall have and maintain written policies and procedures that govern all aspects of the standard and expedited external review processes that include, at a minimum:

1. A quality assurance mechanism in place that ensures:

a. ~~That external~~ External reviews are conducted within the specified time frames and required notices are provided in a timely manner;

b. The selection of qualified and impartial clinical peer reviewers to conduct external reviews on behalf of the impartial health entity and suitable matching of reviewers to specific cases;

c. ~~That the~~ The confidentiality of medical records is maintained in accordance with the confidentiality and disclosure laws of the Commonwealth; and

d. ~~That any~~ Any person employed by or under contract with the impartial health entity adheres to the requirements of this chapter as well as § 38.2-5900 et seq. of the Code of Virginia; and

2. An agreement to maintain and provide to the commission the information set out in § 38.2-5900 et seq. of the Code of Virginia.

B. All clinical peer reviewers assigned by an impartial health entity to conduct external reviews shall be physicians or other appropriate health care providers who meet the following minimum qualifications:

1. Be an expert in the treatment of the covered person's medical condition that is the subject of the external review;

2. Be knowledgeable about the recommended health care service or treatment through recent or current actual clinical experience treating patients with the same or similar medical conditions as the covered person's;

3. Hold a nonrestricted license in a state of the United States and, for physicians, a current certification by a recognized American medical specialty board in the area or areas appropriate to the subject of the external review; and

4. Have no history of disciplinary actions or sanctions, including loss of staff privileges or participation restrictions, that have been taken or are pending by any hospital, governmental agency or unit, or regulatory body that raise a substantial question as to the clinical peer reviewer's physical, mental or professional competence or moral character.

C. In addition to the requirements set forth in subsection A of this section, an impartial health entity shall not be affiliated with or a subsidiary of, nor be owned or controlled by, a health plan, a trade association of health plans, or a professional association of health care providers.

D. 1. In addition to the requirements set forth in subsections A, B, and C of this section, to be qualified to perform an external review of a specified case pursuant to this chapter, neither the impartial health entity selected to conduct the external review nor any clinical peer reviewer assigned by the impartial health entity to conduct the external review may have a material professional, familial or financial conflict of interest with any of the following:

a. The utilization review entity that made the final adverse decision that is the subject of the external review;

b. The covered person whose treatment is the subject of the external review;

c. Any officer, director or management employee of the utilization review entity that made the final adverse decision which is the subject of the external review;

d. The health care provider, the health care provider's medical group or independent practice association recommending the health care service or services subject to the external review;

e. The facility at which the recommended health care service was or would be provided; or

f. The developer or manufacturer of the principal drug, device, procedure or other therapy being recommended for the covered person whose treatment is the subject of the external review.

2. In determining whether an independent review organization or a clinical peer reviewer of the impartial health entity has a material, professional, familial or financial conflict of interest for purposes of subdivision 1 of this subsection, the commissioner may take into consideration situations where the impartial health entity to be assigned to conduct an external review of a specified case or a clinical peer reviewer to be assigned by the impartial health entity to conduct an external review of a specified case may have an apparent professional, familial or financial relationship or connection with a

person described in subdivision 1 of this subsection, but the characteristics of that relationship or connection are such that they are not a material professional, familial or financial conflict of interest sufficient to disqualify the impartial health entity or the clinical peer reviewer from conducting the external review.